

EFFICACY & SCIENCE SUPPORT BRANCH

EFFICACY REVIEW

ANTIMICROBIALS DIVISION

Date In: 08-14-98 Date Out 11-20-98

Reviewed by: Bruce H. Mann Microbiologist

EPA Received Date: 07-10-98

EASSB Received Data: 07-30-98

Lan Code: 68660-U.128

EPA Reg. No. or File Symbol 68660-U

Product Name Proxitane AHC Liquid Sanitizer

Product Type Sanitizer for hard(food contact surfaces)

Company Name Solvay Intercom, Inc.,

MRID No (s): Data were submitted under #445988-01

PM Team /Reviewer: PM-33 Swindell/Kish

Submission Purpose: A new application with efficacy data in
Support of a proposed label claim as a food
contact surface Sanitizer

Formulation: A liquid to be diluted for use (concentration of
active ingredients --- 115 ppms).

ACTIVE INGREDIENT (S)	%
-----------------------	---

Hydrogen peroxide	20.00
-------------------------	-------

Peroxyacetic acid	5.50
-------------------------	------

202.0 Recommendations

202.0 Claims Related to Human health

202.2 Insufficient and Inadequate Data to Finalize the
Efficacy Review:

A. The submitted sanitizing data under MRID number 445988-01 are only reflective of one (1) test sample (Batch #97-013B). However, as the agency indicated the previous efficacy review dated 03-22-97, we recommended and stated that the sanitizing efficacy data listed in item 2 (i) (ii) of DIS/TSS-4 enclosure must be met. Since the submitted sanitizing data are reflective of only one (1) test sample, we are unable to perform a complete efficacy review at this time. To support the proposed sanitization claim for previously cleaned food contact surfaces, the generated data and submitted data must be reflective of each of three (3) different batches, one of which is at least 60 days old.

B. As per the AOAC Official Methods for Germicidal and Detergent Sanitizing Action of disinfectants, the results for the three temperatures (4°C, 20°C and 40°C) which you are proposing must show a 99.999% reduction over the control counts within 30 seconds. For the generated results to be considered valid, the counts on the number controls for the germicide test mixture should fall between $75 \times 125 \times 10^6/\text{ml}$. Refer to the attached AOAC Germicidal and Detergent Sanitizing Test Method for further guidance.

C. In order to make an adequate, systematic and complete review of the tests and generated results, it is essential that the generated efficacy data are reported and presented as indicated in items #1, #2, and #3 of DIS/TSS-3 enclosure.

203.0 Labeling comments:

Until the sanitizing efficacy data requirements are met, a label review for the proposed product cannot be provided.

EFFICACY DATA REQUIREMENTS

Sanitizing rinses (for previously cleaned food-contact surfaces).

Sanitizers applied to food contact surfaces are defined as incidental food additives under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 201 et seq.), and require establishment of a food additive tolerance. Recommendation of a potable water rinse after treatment does not preclude this requirement.

- (1) Halide chemical products. Efficacy of sanitizing rinses formulated with iodophors, mixed halides, and chlorine bearing chemicals must be substantiated with data derived from the AOAC Available Chlorine Germicidal Equivalent Concentration Method.
 - (i) Test requirements. Data from one test on each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against S. typhi are required.
 - (ii) Performance standard. Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. (The reference standard is sodium hypochlorite.)
- (2) Other chemical products. Efficacy of sanitizing rinses formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations must be substantiated with data derived from the AOAC Germicidal and Detergent Sanitizers Method.
 - (i) Test requirements. Data from the test on one sample from each of 3 different batches, one of which is at least 60 days old, against both E. coli and S. aureus are required. When claims for the effectiveness of the product in hard water are made, all required data must be developed at the hard water tolerance claimed.
 - (ii) Performance standard. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and percentage reduction over the control. The minimum concentration of the product which provides the results required above is the minimum effective concentration.

EFFICACY DATA REQUIREMENTS

Reporting of Data

Systematic and complete descriptions of the tests employed and the results obtained are essential for proper review and evaluation of product performance by the Agency. All test reports must include identification of the testing laboratory or organization, when and where the tests were conducted, and the name of the person(s) responsible for the conduct of the tests.

- (1) Recommended Methods. When the Recommended Methods (such as standard AOAC tests) are employed to develop efficacy data, certain minimal information must be provided in the test report. The report must include, but is not limited to, the following:
 - (a) Test employed, and any modifications thereto;
 - (b) Test microorganisms employed, including identification of the specific strain (ATCC or other);
 - (c) Concentration or dilution of product tested and how prepared;
 - (d) Number of samples, batches, and replicates tested;
 - (e) Preparation date of each product batch (individually formulated preparation of the product);
 - (f) Phenol resistance of test microorganisms (actual test results);
 - (g) Identification of all material or procedural options employed, where such choice is permitted or recommended in the test method selected (for example, growth media, drying time for inoculated carriers, neutralizer and/or subculture media, secondary subculturing);
 - (h) Complete report of results obtained for each individual replication;
 - (i) Any control data essential to establish the validity of the test.
- (2) Modification of Recommended Methods. Where Recommended Methods are significantly modified to support specific claims and/or use patterns for a product, the protocol employed for modifying the test must be provided in specific detail with the test report. The applicant may submit the proposed modification for review and evaluation prior to initiation of the test.
- (3) Other Methods. When Recommended Methods, or modification thereto, are not employed to develop efficacy data (such as actual in-use or many kinds of simulated-use testing), complete testing protocols must be submitted with the test reports. All materials and procedures employed in testing must be described in a manner consistent with original research reports published in technical or scientific journals. Where references to published reports or papers are made, copies or reprints of such references should be provided with the test reports. Proposed testing protocols for in-use or simulated-use studies of this kind may be submitted for review and evaluation by the Agency prior to initiation of the tests.